

UNCLAS SECTION 01 OF 08 GENEVA 002798

SIPDIS

PASS USTR FOR ESPINEL, MULLANEY, HAUDA, WINTER, WELLER,
STRATFORD
STATE FOR WILSON, FELT, EB/TPP/IPC, EAP/CM
USDA FOR LASHLEY, SALMON
USDOC FOR ITA/SCHLEGELMILCH
USDOJ PARSKY, CHEMTOB, GAMMS, SHARRIN

E.O. 12958: N/A

TAGS: [EAGR](#) [ETRD](#) [WTRO](#)

SUBJECT: WTO TRIPS COUNCIL October 25-26 2005

1. SUMMARY: The TRIPS Council meeting took place on Tuesday and Wednesday October 25-26, 2005. Mr. CHOI Hyuck of Korea chaired the meeting. There was an informal session held in the morning of October 25, with the formal session beginning on the afternoon and continuing to the next day. In particular, discussion continued on the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. As to the relationship of TRIPS and the CBD, new documents were tabled by Peru and a group of developing countries, and Brazil and India requested new negotiations on patent disclosure requirements. The least-developed countries (LDCs) submitted a request to extend the transitional period for TRIPS compliance by another 15-years. The formal meeting was suspended to allow for further discussion on access to medicines, the relationship of TRIPS and CBD, the LDC extension request, and issues concerning non-violation and situation complaints. END OF SUMMARY

INFORMAL SESSION

2. The TRIPS Council met in informal session on the morning of October 25th. The Chair raised three issues for discussion: (1) the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, (2) Non-violation Nullification Argument, and (3) LDC extension request.
3. Brazil and India requested to be included in the small group consultations that are occurring, noted concerns over the status of the Chairman's Statement as part of the solution, and that the August 30th Decision is the basis for the amendment. Brazil noted that Members that are not consulted could not be considered bound by such consultations and that "no solution would be better than a bad solution."
4. India and Argentina noted that are apparently several "informal" papers being circulated and discussed, but only the Africa Group paper is formally on the table, so they noted that they consider the African Group proposal from December 2004 as the basis for work.
5. The USDEL indicated that consultations on this matter have been helpful. The USDEL reiterated that the quality of the amendment should be the same as the agreement reached on August 30th. It was noted that the U.S. is not seeking to elevate or diminish the status of the Chairman's Statement, and that the objective is to preserve the agreement reached. The USDEL concluded by noting that the amendment process should be a technical exercise and not a substantive one.
6. The EC agreed that the process should be one of a technical nature and legally secure, and welcomed intensified consultations on the issue.
7. Canada stated that it has circulated a paper noting in detail how Canada has implemented the solution. Canada also stated that it has an interest in ensuring that the result of the amendment process does not result in a change in Canada's legislation.
8. Chair concluded, noting that he did not know when he would be able to give better ideas as to the timing of further consultations.
9. On NVNI, the Chair stated the status of Members' views on four recommendation options that are before the Council: 1) a majority have stated that NVNI is inapplicable to TRIPS; 2) some have stated that the NVNI moratorium should be extended; 3) a couple have stated that NVNI is applicable to TRIPS in the context of DSB rules; and 4) one Member states that the moratorium should expire at the Ministerial. Colombia added that it has received instructions from Capital, and that it will maintain its long-standing position that NVNI is inapplicable to TRIPS. The Chair concluded, noting that that there is no emerging consensus and that he will report to the General Council that work will need to continue in the run-up to the Hong Kong

Ministerial.

- ¶10. On the LDC extension request, no delegation took the floor. It was discussed at the formal session.

FORMAL SESSION

FOLLOW-UP TO REVIEWS OF NATIONAL IMPLEMENTING LEGISLATION ALREADY UNDERTAKEN

- ¶11. Egypt responded to follow-up questions submitted by Switzerland and the United States. Both the U.S. and Switzerland thanked Egypt for its responses and stated that it agreed with the Chair that the regular review of Egypt should be deleted from agenda. It was noted that follow-up questions can be posed at any time.

Decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health

- ¶12. Brazil began the discussion by noting that its country takes the access to medicines issue and the amendment process very seriously. Brazil commented on its publicly funded AIDS program and that the costs of medicines in Brazil weighs heavily on Brazilian taxpayers. Brazil noted that a delicate balance was struck to reach agreement in August 2003. Brazil stated that there is no reference made in the General Council Decision to the Chairman's Statement and that paragraph 11 of the Decision calls for the amendment to be based, where appropriate, on the Decision and not on the Statement. Brazil added that it could not agree to a procedure that would change the legal status of the Decision or the Statement. Brazil noted concerns that some Members make reference to "agreed package" or "agreed solution" and stated that the amendment mandate in the Decision mentions only the Decision itself. Brazil continued, noting that the asterisk that was included in document WT/L/540 (the asterisk states that the Decision was adopted by the General Council in the light of a Statement read out by the Chairman) should be removed as it was added after the Decision was adopted. Brazil added that while the Secretariat issued a Corrigendum that contains additional language to that asterisk claiming that it is a Secretariat note for administrative purposes only, this correction does not solve the problem and the asterisk should be removed. Brazil stated that the Africa Group proposal for the amendment is the only proposal on the table, and provides a very good basis for the amendment. Brazil argued that there are elements in the Africa Group proposal that are quite convincing (ie., removing redundancies when transposing it to legal text for amendment of the agreement; regional patent systems probably not appropriate to include in text of TRIPS). Brazil concluded by stating that it is an interested party in whatever consultations the Chair carries out.
- ¶13. Nigeria made a positive statement that it considers the consultations to be the most viable way of reaching some decision before the Ministerial.
- ¶14. India noted its substantive interest in the issue, both as supplier and also for its citizens. India stated that it agrees that the Africa Group proposal is a good basis for work. Added that the Chairman's Statement is not a part of the Decision itself and that the subject matter for amendment is the Decision. India concluded, noting that it fully supports Brazil's statement regarding the asterisk.
- ¶15. Argentina reiterated that the Africa Group proposal is the basis for work on the amendment. Noted that there are elements in the proposal that deserve close attention. Argentina noted that it agreed with the proposal that certain aspects of the Decision should not be included in the amendment. Noted that the Decision is the only agreement among the parties that exists, and added that it does not recall any agreement on placement and use of the asterisk. Argentina stated that the text should stand as it was formulated in the General Council.
- ¶16. Philippines indicated that it is committed to remaining constructive during the consultations and that it is ready to participate in any consultations on the matter. Noted that it continues to maintain that the Africa Group proposal is important basis for the discussions. It stated that any decision should be considered in the humanitarian context in which the Decision was negotiated.
- ¶17. China stated that it is in process of drafting implementation regulations for both domestic use and for export under the Decision. China added that the amendment will provide legal certainty for all Members.
- ¶18. The USDEL stated that the consultations have been helpful for the amendment process. The U.S. reiterated its position that there needs to be an express reference of the Chairman's Statement and the Decision in the amendment. The

process should not reopen the solution and noted that they view it to be a technical exercise. With respect to the asterisk, the U.S. stated that the corrigendum was unnecessary and that certainly no further action should be taken by the Secretariat.

- ¶19. New Zealand and Australia agreed with the U.S. intervention that the process should be a technical exercise. They noted that the question is not whether to deal with the Chairman's Statement but how should it be described in the amendment.
- ¶20. In response to Brazil's comments regarding whether the Chairman's Statement is interpretive context, the EC noted that the definition of "context" in the Vienna Convention is defined in Article 31 paragraph 2a and the Statement is context for interpretation. India added that the EC's explanation reconfirms fears about the unclear status of the Chairman's Statement.
- ¶21. Korea and Singapore asked that the voluntary opt-out not be turned into a legal obligation during the amendment process.
- ¶22. The Chair stated that the EC paper remains as a non-paper and that he will continue to hold consultations with Members.

REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B), THE RELATIONSHIP OF THE TRIPS AGREEMENT AND THE CBD AND THE PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE.

- ¶23. PERU PRESENTED A NEW PAPER ON SPECIFIC CASES RELATED TO THEIR BIOPIRACY CONCERNS. "CAMU CAMU" WAS DISCUSSED AS AN EXAMPLE. IT IS A WILD FRUIT SIMILAR TO CHERRY THAT COMES FROM THE AMAZON AND CONTAINS HIGH LEVELS OF VITAMIN C. PERU NOTED THAT IN THE PAST SEVERAL YEARS, THERE HAVE BEEN ATTEMPTS TO INDUSTRIALIZE CAMU CAMU FOR FOOD AND COSMETICS. PERU ADDED THAT THERE IS A NEED FOR A MANDATORY DISCLOSURE OF SOURCE REQUIREMENT, AS PATENT SYSTEMS HAVE FAILED TO PREVENT PROBLEMATIC CIRCUMSTANCES INVOLVING THE PATENTING OF GENETIC RESOURCES. PERU REITERATED THAT IT SEEKS TO AMEND TRIPS ARTICLES 27 & 29 TO INCLUDE MANDATORY DISCLOSE OF SOURCE OF ORIGIN TO RESULT IN TRANSPARENCY AND SECURITY AND TO HELP PERU AVOID HAVING TO CONDUCT STUDIES OF WHICH PATENTS WERE ERRONEOUSLY GRANTED. PERU ALSO ADDED THAT THE AMENDMENTS WOULD HELP THE PATENT SYSTEM MEET THE DEVELOPMENT NEEDS OF THEIR PEOPLE.
- ¶24. INDIA INTRODUCED ITS NEW SUBMISSION ON BEHALF OF BOLIVIA, BRAZIL, CUBA AND PAKISTAN. THE PAPER IS IN RESPONSE TO THE CONTRACT BASED APPROACH PRESENTED IN THE JUNE SUBMISSION OF THE UNITED STATES. INDIA NOTED THAT WHILE THE CBD DOES NOT CONTAIN PATENT DISCLOSURE REQUIREMENT PROVISIONS, THE CBD DID CONTAIN OBLIGATIONS THAT COUNTRIES SHOULD NOT ALLOW INTELLECTUAL PROPERTY TO RUN CONTRARY TO CBD OBLIGATIONS AND A NEW TRIPS DISCLOSURE REQUIREMENT WOULD ENSURE THIS. INDIA STATED THAT THE KEY PROBLEM RELATED TO THE ACCESS TO GENETIC RESOURCE ISSUE IS WITH RESPECT TO TRANSBOUNDARY ACTIONS AND THAT ONLY AN INTERNATIONAL BINDING SOLUTION WILL SOLVE THE ISSUE. INDIA ALSO STATED THAT "BAD PATENTS" IS ALSO AN ISSUE AND THAT IT WILL ATTACH A LIST OF BAD PATENTS IN A FUTURE SUBMISSION. INDIA CONTINUED BY NOTING THAT ERRONEOUSLY GRANTED PATENTS ARE NOT RARE EXCEPTIONS, BUT THE BURDEN OF GETTING A PATENT REVOKED IS HIGHER THAN THE AMENDMENT IT SEEKS. IT WAS NOTED THAT IS PROPOSAL WILL NOT FORCE COUNTRIES TO ENFORCE THE LAWS OF OTHER COUNTRIES. INDIA CONCLUDED BY NOTING THAT IT WELCOMES SUGGESTIONS ON AMENDMENT LANGUAGE.
- ¶25. The USDEL stated that there was more vigor in the discussions as there are more facts and issues being brought forth for discussion. The U.S. stated that national contract-based systems are essential elements of any system regarding access to genetic resources, and continues to consider that new patent disclosure requirements are not effective in meeting the concerns raised. The answer is tailored national laws outside the patent system that regulate conduct in this area. The USDEL continued by noting the negative effects new disclosure requirements will have on biotech, as an engine of economic growth. As result, the amendments in TRIPS could be negative for both developed and developing countries. If patents are invalidated, the proposals aim at advancing benefit sharing will not be realized. The USDEL mentioned that the IGC at WIPO recently had its mandate renewed on TK/CBD/GR and noted that it looks forward to the IGC's consultations that will be informative to the TRIPS Council's work.
- ¶26. The USDEL also responded to questions posed by Switzerland at the June meeting. The first was (1) How would a purely national approach address problems arising with regard to trans-boundary access and benefit sharing, that is, cases where genetic resources and traditional knowledge are used outside the scope of application of the national solutions advanced by the United States? The USDEL noted

that a contract-based system can provide great flexibility concerning trans-boundary actions and provide an effective solution by including appropriate provisions for when disputes arise, such as choice of forum, choice of law, and/or binding international arbitration clauses. These provisions would be helpful whether the dispute is in country or "transboundary." The contract could also specify terms regarding the nature of the benefit-sharing arrangement, regardless of the country in which the commercialization takes place. Similarly, under a contract-based system, a monitoring plan for commercial applications could be established, particular to the facts of each case.

127. The second was how would a purely contractual approach address cases where no contract on access and benefit sharing has been concluded between the provider and the user of genetic resources and traditional knowledge? The USDEL noted that cases in which no contract has been concluded in violation of the domestic ABS regime, as in any other situation where a company fails to comply with domestic regulation, would be governed by the requirements and penalties of the domestic access and benefit-sharing regime in place. As a result, such an absence would be enforced by criminal and/or civil penalties specifically designed for the ABS regime.

128. The third question was how would the proposed approach take into account the generally long-term nature of research and development activities involving genetic resources? The USDEL noted that an ABS system could include regular reporting requirements for researchers on the nature of their research, including whether any new commercial applications are envisioned. The USDEL continued by noting that a contract-based system is a better mechanism of addressing long-term R&D activities, since a patent may, and sometimes does, expire on a newly identified product before a commercially valuable use of that product is discovered. Furthermore, a contract based system can better control the distribution of the genetic resource, if a patent can be applied for, and how that patent is controlled.

129. The USDEL also responded to the questions posed by India at the June meeting regarding Turmeric. The U.S. stated the turmeric patent was filed by two Indian nationals working in the U.S., and that the patent disclosure does, in fact, disclose India as the country of traditional origin of turmeric. So a disclosure of origin would not have prevented the situation from occurring. Moreover, the U.S. noted that the issue in this case was information relevant to inventorship and the state of the prior art. The applicant was already under a type of disclosure requirement in the U.S. - that of disclosing information material to patentability. In the turmeric case, information regarding healing properties of turmeric would have been material to patentability but such information was not disclosed by the applicant. The USDEL noted that the re-examination process allowed for prior art to be brought to the attention of the USPTO, a reexamination was filed, and the prior art was applied against the claims in an appropriate and effective manner, leading to cancellation of all claims in the turmeric situation. This took place over 19 months. The USDEL reiterated that it fully supports efforts to strengthen options to prevent mistakenly granted patents, such as the requirement to disclose information material to patentability, the use of organized databases, and post-grant opposition proceedings, such as reexamination.

130. Canada provided questions to the U.S. concerning its position: 1) would the authorities that would be involved in monitoring a contract-based system be national or international in nature, and if international, under which jurisdiction would they operate; and 2) in a scenario where sanctions are put into place outside of patent system, what impact would disclosure requirement have on patent system? Canada also provided questions to the EC regarding their textual changes proposed and how would they address access to benefit sharing arrangements. Canada also asked the demandeurs to clarify who would be the appropriate party in a misappropriation suit; would it be the country of source or country of origin named in the patent? Canada asked Switzerland who would determine which government agencies are part of pre-qualified list to help enforce prior informed consent and access to benefit sharing and what role would they play?

131. Japan noted that it has guidelines for access to genetic resource documents to help companies understand how to use the CBD. Japan noted that it does not support the proposals for patent disclosure requirements made by various developing countries.

132. Thailand, Ecuador, Bolivia and Dominican Republic supported India and Brazil's submissions.

133. In response to Brazil's proposal that the Chair make a recommendation to the TNC/GC to begin negotiations on patent

disclosure requirements, the USDEL noted that it does not support Brazil's request and it would not be appropriate for Chair to make a statement on the matter when there are a wide divergence of views on the issue. Japan supported the U.S. intervention, agreeing that it would be premature to do anything but continue discussing the issue.

134. The Chair noted that he will report to the TNC/GC that there is no consensus and wide divergence of views. The Chair will keep this agenda item open on a suspended agenda.

NON-VIOLATION AND SITUATION COMPLAINTS

135. The following delegations intervened noting that NVNI complaints should not apply to TRIPS: Canada, Colombia, Argentina, Peru, Malaysia, Brazil, Chile, Thailand, EC, Ecuador, India, Indonesia, Cuba and Venezuela. India further added its interpretation that TRIPS Article 64 will not allow for NVNI complaints if the moratorium expires.
136. The USDEL noted that it supports application of NVNI in TRIPS and that it expects the moratorium to end at the Sixth Ministerial Conference.
137. Japan and Switzerland stated that they support further work on scope and modalities.
138. The Chair noted that further consultations will need to take place, as the Council cannot currently make a recommendation to the TNC. The Chair noted that he will report to the General Council on the work undertaken on the matter.

TRANSITION PERIOD FOR LEAST-DEVELOPED COUNTRIES-REQUEST FOR EXTENSION

139. Zambian Ambassador introduced LDC proposal to extend transitional period for TRIPS Compliance by An additional 15 years. He stressed points concerning that resource and economic difficulties LDCs face and the costs of implementing TRIPS obligations. Tanzania, Uganda, Cambodia, Senegal, Lesotho all supported Zambia's statement.
140. Argentina and Brazil commented that no evidence exists that IPRs are good for developing countries, citing their Development Agenda proposals in WIPO. They stated that many developing countries are questioning the benefits of IP and TRIPS in their economies and whether it actually leads to technology transfer and development.
141. Japan, U.S., EC and Switzerland all indicated that a more country-by-country approach to the extension request would be more feasible in order to ensure that all countries can implement and benefit from the TRIPS Agreement. The USDEL specifically noted the well-documented links between IP and development.
142. Norway stated that it supported the request but also stated that IP is essential to development and would come back to the issue at a later time.

REVIEW OF THE APPLICATION OF THE PROVISIONS OF THE SECTION ON GEOGRAPHICAL INDICATIONS UNDER ARTICLE 24.2

143. On the Article 24.2 review of the protection for geographical indications, the EC stated that to further work in this area the Council should develop an agenda based on the Secretariat's compilation document developed last year on the 24.2 checklist responses. The EC added that the discussion should focus on examining the application of the GI provisions, but should not focus on Members' implementation of provisions.
144. The USDEL opined that it continues to support a walk through of the GI provisions paragraph by paragraph, and that it would be premature to structure the discussions based on the headings in the Secretariat's document. The U.S. noted that it is interested in attending any consultations on the matter.
145. The Chair noted that it will revert the matter to the next meeting.

FOLLOW-UP TO THE SECOND ANNUAL REVIEW UNDER PARAGRAPH 2 OF THE DECISION ON THE IMPLEMENTATION OF ARTICLE 66.2 OF THE TRIPS AGREEMENT

146. Rwanda and Zambia noted their appreciation for the reports submitted by developed countries on incentives to encourage business to provide technology transfer to LDCs. Rwanda specifically noted that more measures should be adopted to encourage technology transfer, and suggested that a committee of experts comprised of developed countries, LDCs, and specialists formulate recommendations to make tech transfer policies more effective.

TECHNICAL COOPERATION AND CAPACITY-BUILDING

147. Developed countries submitted their reports on technical assistance programs in 2005. India raised an item in the Australian report regarding GI's that they claimed was mere advocacy of positions and not technical cooperation. Australia indicated that while they did have an advocacy session, they stated that a work-shop was also held with trademark examiners.
148. Brazil also noted concern with respect to the technical assistance activities reported by WIPO, noting that WIPO mischaracterized the Brazil, Argentina proposal at WIPO regarding the Development Agenda.

ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS-COMMUNICATION FROM THE EUROPEAN COMMUNITIES

149. The EC noted its paper, tabled at the June meeting, concerning enforcement matters. The EC noted that it will elaborate on proposals made in the communication in the future. The EC added that the level of enforcement rules in TRIPS can be improved. Moreover the concern over the lack of enforcement is being debated at G8, Interpol, OECD, WIPO, and should be discussed at the WTO as well. The objective of the discussions will be to identify solutions regarding WTO compliance with enforcement requirements under TRIPS. The EC requested that the Secretariat produce a synopsis of Members' contributions to the enforcement checklist in IP/C/W/5. With respect to the discussion in the Council, the EC noted that it should seek to: identify difficulties in implementing TRIPS enforcement provisions; identify the appropriate mechanisms for addressing the difficulties; and coordinate a response at the TRIPS level through various tools, such as best practices. The EC noted that border measures should be the first topic of discussion.
150. Japan stated that the recent development of high technology and mass distribution has prompted growth in pirate and counterfeit goods. There have been more reports that these activities are linked to terrorist groups. Japan noted that it welcomes the EC proposal which presents very helpful points. Japan noted that in future meetings, Members should pay attention to discussions going on in other fora such as WIPO, G8 and OECD. Discussions in TRIPS Council should include those noted in paragraph 26 of the EC proposal: procedures to preserve evidence; calculating damages methodology; sanctions available at civil and criminal level; information right; and use of provisional and protective measures, custom measures and their availability for export and transit.
151. Brazil reiterated concerns expressed in last meeting of TRIPS regarding EC proposal. It stated that it fully agrees that piracy and counterfeiting are problems all Members should address. But Brazil noted that it disagrees with the focus and activities it proposes the TRIPS Council to undertake. Brazil noted that implementation of TRIPS is still an ongoing process for many, if not most, developing countries and the Council is entertaining an LDC proposal for extension of the burdensome TRIPS requirements. It noted that the EC's proposal is unfair, in that, it would have the Council playing a de facto norm-setting role. Brazil also noted that this proposal would be redundant with the work going on at the WIPO enforcement body, which has also turned down a TRIPS-plus norm-setting role. Brazil asked that the item be removed from agenda of all future TRIPS Council meetings.
152. Argentina stated that the TRIPS Council agenda already allows for discussion regarding TRIPS oversight of Members implementation. Argentina also noted that the EC's proposal should be off the agenda, as it does not represent the interest of the majority of the members.
153. Canada noted that it is willing to discuss this issue at future meetings.
154. The USDEL noted that the issue is an appropriate and legitimate exercise for the Council to continue discussions. The U.S. noted that it will need more time to consider the details of the proposal, and noted that Council should focus at present on important work already before us for the Ministerial run up when we consider how to handle enforcement discussions for the future. The EC responded noting that it will provide more detail regarding its proposal after the Ministerial.
155. India, Egypt, China, Philippines, and Chile noted support for Brazil's recommendation that it be removed from the agenda.
156. Switzerland noted that this is an important issue to be addressed by Council. In view of the Ministerial, Switzerland noted that it probably was not the time to do it

now in the run-up. But Switzerland noted that it wants to discuss this issue again at the next formal meeting.

Korea noted that the issue of enforcement is being discussed at APEC, WIPO, and the OECD. Korea added that when the EC proposal is available as formal document, they will comment on it.

157. The EC stated that it views the issue to be an appropriate discussion item for the Council, and that they are not trying to make the Council a norm-setting body, or a tribunal for how members are enforcing TRIPS.

158. Chair noted that this matter will be reverted to the next meeting.

OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

159. Brazil and other delegations expressed support for observer status for the South Centre and the CBD. While Egypt reserved its right to come back with a written opinion, the USDEL noted concern about granting observer status for several of the international observer organizations, including that guidelines have not be established by the General Council.

OTHER BUSINESS

160. The U.S., Switzerland and Japan submitted an Article 63.3 request for details on specific enforcement cases in China. China noted it will study the requests, but stated it will not take any more obligations than required, and that Members should not take action based on unilateral interpretations. Japan, Switzerland and the U.S. noted that they submitted these requests with the hope of enhancing understanding of IPR enforcement in China and look forward to China's responses.

161. The Chair also announced the following tentative dates for TRIPS Council sessions in 2006: 14-15 March 2006, 14-15 June 2006, and 24-25 October 2006.